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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,493	09/23/2003	Gil M. Vardi	CWIRE-001DIV	3988
1473	7590	07/14/2005	EXAMINER	
FISH & NEAVE IP GROUP			FOREMAN, JONATHAN M	
ROPES & GRAY LLP			ART UNIT	
1251 AVENUE OF THE AMERICAS FL C3			PAPER NUMBER	
NEW YORK, NY 10020-1105			3736	

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary

Application No.

10/669,493

Applicant(s)

VARDI ET AL.

Examiner

Jonathan ML Foreman

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

New grounds of rejection are contained within this Office Action. Accordingly this action has been made Non-Final.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 15, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,144,959 to Gambale et al.

In regards to claims 15, 16 and 17, Gambale et al. discloses providing a guidewire having a core wire (10) with proximal section and tapered distal section (Figure 1), and plating gold onto a plurality of predetermined locations of the core (Col. 3, lines 28 – 30). However, Gambale et al. fails to disclose coating portions of the distal section of the core wire with a mask; exposing the distal portion beneath the mask at a plurality of predetermined locations; electroplating gold onto the predetermined locations; and removing the mask. However Gambale et al. discloses coating portions of a distal section of the guidewire with a mask; exposing the distal portion beneath the mask at a plurality of predetermined locations (Col. 5, lines 47 – 52); electroplating gold onto the predetermined locations (Col. 5, lines 35 – 37; Col. 4, lines 17 – 21); and removing the mask (Col. 5, lines 53 – 54). It would have been obvious to one having ordinary skill in the art to use the method as disclosed by Gambale et al. for plating gold at a plurality of predetermined locations of the distal

Art Unit: 3736

section of the guidewire to plate gold at a plurality of predetermined locations of the distal section of the core wire to ensure that plating is only deposited on the desired areas.

3. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,144,959 to Gambale et al. as applied to claim 15 above, and further in view of U.S. Patent No. 5,437,288 to Schwartz et al.

In regards to claim 18, Gambale et al. fails to disclose coating the guidewire with a lubricious coating. Schwartz et al. discloses electroplating a distal portion of a guidewire with gold, and providing the guidewire with a lubricious coating (Col. 5, lines 51 – 56). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a lubricious coating as taught by Schwartz et al. with the guidewire as disclosed by Gambale et al. in order to increase the mobility of the guidewire within a vessel (Col. 5, lines 43 – 46).

4. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,144,959 to Gambale et al. as applied to claim 15 above, and further in view of U.S. Patent No. 6,455,783 to Tsukada et al.

In regards to claim 19, Gambale et al. discloses removing the mask (Col. 5, lines 53 – 54), but fails to disclose chemically dissolving the mask. However, Tsukada et al. discloses an electroplating process wherein the mask is removed by chemically dissolving the mask (Col. 8, lines 55 – 56). It would have been obvious to one having ordinary skill in the art at the time the invention was made to remove the mask as disclosed by Gambale et al. by chemically dissolving the mask as taught by Tsukada et al. so as to remove the mask in its entirety.

5. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,144,959 to Gambale et al. as applied to claim 15 above, and further in view of U.S. Patent No. 65,406,960 to Corso, Jr.

In regards to claim 20, Gambale et al. fails to disclose forming indentations at the predetermined locations prior to the depositing of materials. However, Corso, Jr. discloses a guidewire wherein the radiopaque material is deposited in previously formed indentations on the core wire (Col. 5, lines 45 – 47). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the process as disclosed by Gambale et al. to include the step of depositing the radiopaque material in previously formed indentations as taught by Corso, Jr. in order to provide a smooth surface along the length of the core wire.

6. Claims 15 - 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,865,767 to Frechette et al. in view of U.S. Patent No. 5,144,959 to Gambale et al.

In regards to claims 15 - 18, Frechette et al. discloses providing a guidewire having a core wire (10) with proximal section and tapered distal section (22), and electroplating plating gold onto a plurality of predetermined locations of the core (Col. 4, lines 44 – 56). Frechette et al. discloses a lubricious coating (Col. 4, lines 44 – 58). However, Frechette et al. fails to disclose coating portions of the distal section of the core wire with a mask; exposing the distal portion beneath the mask at a plurality of predetermined locations; electroplating gold onto the predetermined locations; and removing the mask. However, Gambale et al. discloses coating portions of a distal section of the guidewire with a mask; exposing the distal portion beneath the mask at a plurality of predetermined locations (Col. 5, lines 47 – 52); electroplating gold onto the predetermined locations (Col. 5, lines 35 – 37; Col. 4, lines 17 – 21); and removing the mask (Col. 5, lines 53 – 54). It would have been obvious to one having ordinary skill in the art to use the method as taught by Gambale et al. for plating gold at a plurality of predetermined locations of the distal section of the guidewire to plate gold at a plurality of predetermined locations of the distal section of the core wire as disclosed by Frechette et al. to ensure that plating is only deposited on the desired areas.

Art Unit: 3736

the core wire as disclosed by Frechette et al. to ensure that plating is only deposited on the desired areas.

7. Claims 15 – 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,253,653 to Daigle et al. in view of U.S. Patent No. 6,174,329 to Callol et al.

In regards to claims 15 – 18, Daigle et al. discloses a method for manufacturing a guidewire including providing a core wire (5) having proximal and distal sections; plating a radiopaque material including gold (Col. 2, lines 42 – 44) at predetermined locations on the distal section (Col. 4, lines 37 – 40); tapering a distal section (5b; Col. 3, lines 21 – 22); and coating the guidewire with a lubricious coating (Col. 3, line 67 – Col. 4, line 4). However, Daigle et al. fails to disclose coating portions of the distal section with a mask; exposing the core wire at a plurality of predetermined locations beneath the mask; electroplating gold onto the predetermined locations; and removing the mask. Callol et al. discloses a method for manufacturing an intraluminal device including coating portions of the device with a mask (Col. 6, lines 8 – 10); exposing the core wire at a plurality of predetermined locations beneath the mask (Col. 6, lines 12 – 15); and electroplating gold onto the predetermined locations (Col. 6, lines 16 – 18). The mask is inherently removed before using the device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the steps of coating a portion of the distal section of the guidewire as disclosed by Daigle et al. with a mask; exposing the core wire at a plurality of predetermined locations beneath the mask; electroplating gold onto the predetermined locations; and removing the mask as taught by Callol et al. in order to ensure the correct positioning of the radiopaque material on the gauging section (5) of the guidewire.

Response to Arguments

8. Applicant's arguments filed 4/15/05 have been fully considered but they are not persuasive. In regards to Gambale et al., Applicant asserts that Gambale et al. fail to disclose exposing the core wire beneath the mask at a plurality of predetermined locations. Applicant states that Gambale et al. teaches away from including multiple elements having radiopaque effects. However the Examiner disagrees. The guidewire is exposed beneath the mask at two locations on opposite sides of the mask (Col. 5, lines 47 – 52). The Examiner considers these two locations to be a plurality. In regards to Schwartz et al., Applicant asserts that Schwartz et al. fails to neither describe nor suggest depositing radiopaque material on the guidewire. However, at Col. 3, lines 53 – 56, Schwartz et al. states, "The distal tip 12 would also be plated with a radio opaque material, such as gold, to enable the practitioner to view the distal tip on an X-ray viewing screen.". In regards to Tsukuda et al., Applicant asserts that Tsukuda et al. is not directed to guidewires and is considered to be non-analogous art. In response to applicant's argument that Tsukuda et al. is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Tsukuda et al. is considered to be in the field of applicant's endeavor in that it is related to a process of manufacturing involving electroplating. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was

Art Unit: 3736

made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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